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W00718R

**Certified Mail**  
**Return Receipt Requested**

December 6, 2006

Erlinda N. Figueroa  
Compliance Officer  
San Francisco District  
US Food and Drug Administration  
1431 Harbor Bay Parkway  
Alameda, California 94502-7070

Re: Response to Warning Letter for Honolulu Fish & Seafood Company, dated 11/28/06

Dear Ms. Figueroa,

We received the above referenced Warning Letter on Tuesday, December 5. We have reviewed the findings described in the letter and have taken the following actions to comply in response. There were 4 significant violations listed in the Warning Letter. They are paraphrased below along with a description of how our company is responding to comply.

**Need HACCP Plan for refrigerated vacuum-packaged scombroid toxin forming species.**

At the time of the inspection and prior to the Warning Letter, our company used both true vacuum (non permeable) and oxygen permeable bags (██████████) for fish fillets. We have decided to discontinue the use of any true vacuum bags in our operation and to use only oxygen permeable bags and other materials that guarantee a minimum oxygen transmission rate of 10,000 cc/m2/24 hours. All other fish packaging materials used are oxygen permeable and do not create a low oxygen or anoxic package environment. We have segregated and will remove all true vacuum bags from our plant. Please see revised Hazard Analysis and HACCP Plan.

**Need to modify chilled storage temperature monitoring for scombroid toxin forming fish.**

We have purchased a [REDACTED] digital temperature data logger system to monitor refrigerator temperatures. This system is set to record temperatures at 1 minute intervals, 24 hours per day, 7 days per week. Visual checks of the refrigerator temperature data logger chart will be done at the beginning of each working day; this reviews the temperature record of the period since the last visual temperature check. In addition to this new step; we will still conduct our manual chill temp checks [REDACTED] daily and record them in our daily SSOP reports. Please see revised HACCP Plan, example print out of data logger chart plotting 1 minute intervals 24/7, photograph of installed system, and the receipt from the data logger manufacturer.

**Need to modify corrective action for tuna and scombroid species at the chilled storage step.**

The corrective actions for the Chilled Storage CCP for "Tuna and other scombroid species" has been modified. These now include histamine testing as part of the corrective action options. Please see revised HACCP Plan. The new corrective action sequence is as follows.

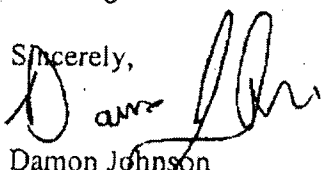
*"Adjust or repair cooler. Assess product temperature. If <40 °F, accept. If, >40 °F and <45 °F, chill fish quickly to <40 °F in ice or in a working refrigerator. After fish are <40 °F, conduct sensory exam on all fish. Determine how long fish temperatures were >40 °F. If < 4 hours cumulatively, accept all fish that pass sensory exam and reject those that fail. If > 4 hours cumulatively, reject all fish that fail sensory exam. test fish that pass sensory exam for histamine. Accept fish containing <50 ppm and reject fish containing >50 ppm".*

**Need to modify critical control point at receiving for scombroid species.**

Our Hazard Analysis and HACCP Plan at the time of inspection included descriptions of fish "received from boats using ice or rsw". This is not entirely accurate in that these types of vessels are the origin of the fish we purchase and receive, but Honolulu Fish Company does not receive these fish directly from fishing vessels. Therefore, we have modified the language in our Hazard Analysis and HACCP Plan to reflect this situation more clearly. Our fish are purchased from companies that are responsible for ensuring safe fish handling practices and scombrotoxin controls at sea on fishing vessels. For this reason, vessel harvest records or representative histamine testing at receipt are not appropriate procedures for our company HACCP Plan. Please see revised Hazard Analysis and HACCP Plan.

We look forward to your comments and further guidance on improving our HACCP Plan. We hope that we have resolved the issues raised and can anticipate removal of the Warning Letter at the earliest possible date.

Sincerely,

  
Damon Johnson  
Vice President  
Honolulu Fish Company